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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/827,495	04/06/2001	Leticia Delgado-Herrera	6688.US.01	5748

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EXAMINER	
WILLIAMS, LEONARD M	
ART UNIT	**PAPER NUMBER**
1617	

DATE MAILED: 01/27/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/827,495	DELGADO-HERRERA ET AL.	
	Examiner	Art Unit	
	Leonard M Williams	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 September 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *9-13* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *9-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Detailed Action

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 09/27/2004 has been entered.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 9-13 are rejected under 35 U.S.C. 102(b) as being anticipated by Goldenburg (Clinical Therapeutics, Vol. 21, No 3, March 1999).

Goldenburg teaches on pages 437-438 that a group of dialysis patients receiving calcitriol to moderate their parathyroid hormone secretion and to keep their calcium and phosphorous levels in homeostasis, were treated with paricalcitol (1a,25-dihydroxy-19-nor ergocalciferol) for a period of 4 weeks anticipating the method for treating

hypocalcemia with 1α,25-dihydroxy-19-nor ergocalciferol of claim 9, the method where it is administered daily for 1-4 weeks of claim 11, the method wherein the 1α, 25-dihydroxy-19-nor ergocalciferol is combined with a non-toxic pharmaceutically acceptable carrier of claim 12 (though not specifically described in the reference one of ordinary skill in the art can infer that the medications were administered in a non-toxic pharmaceutically acceptable carrier) and the method wherein the hypocalcemia reflects a blood/tissue maldistribution of calcium of claim 13. Neither the serum calcium, phosphorous, or parathyroid hormone levels altered after change to paricalcitol. Goldenburg teaches on page 437 results from three phase III clinical trials on the efficacy of paricalcitol which included dosages ranging from 0.04 μg/kg to 0.12 μg/kg anticipating the 0.1 μg to 2 mg per day of claim 10.

Claims 9-13 are rejected under 35 U.S.C. 102(b) as being anticpated by DeLuca et al. (US Patent No. 5246925). DeLuca et al. teach, in col. 1 line 20 to col. 2 line 65, that metabolites of vitamin D are potent regulators of calcium homeostasis in animals and that derivatives of 19-nor vitamin D which include 1α,25-dihydroxy-19-nor ergocalciferol are useful in the treatment of hyperparathyroidism. DeLuca et al. teach in col. 8 lines 20-45, that the 19-nor vitamin D compounds can be formulated with non-toxic pharmaceutically acceptable excipients and that suitable dosages are from 1-500 μg per day anticipating the methods of claims 9-13.

The examiner respectfully notes that the term "ICU-associated hypocalcemia" is being treated as "hypocalcemia". The specification defines "ICU-associated hypocalcemia" as "...hypocalcemia that occurs in patients hospitalized in an Intensive

Care Unit setting". Stedman's Medical Dictionary 27th edition defines hypocalcemia as "Abnormally low levels of calcium in the circulating blood; commonly denotes subnormal concentrations of calcium ions". The addition of "ICU-associated" to the term hypocalcemia only specifies a location where the hypocalcemia is occurring with no connection of cause/effect and no indication that the location is of particular importance. The causes of hypocalcemia are varied but often it is associated with acute conditions that would require admission to the ICU of a hospital with examples being sepsis due to an infection, liver failure, pancreatitis, or end stage renal disease. The fact that these disease states may require ICU admission and that hypocalcemia may occur to the said patient is irrelevant to the said patient's location.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leonard M Williams whose telephone number is 571-272-0685. The examiner can normally be reached on MF 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

LMW

SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER